REMARKS

Applicants have received and carefully reviewed the Office Action of the Examiner mailed October 18, 2011. Applicants respectfully traverse (and do not concede) all objections, rejections, and adverse assertions made by the Examiner. With this paper, claim 35 has been amended. Support for the amendments is found in the specification, claims, and drawings as originally filed. No new matter has been added. Claims 22, 24-28, and 30-37 remain pending, with claims 31-34 and 36 previously withdrawn. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections under 35 U.S.C. § 103

Claims 22, 24-26, 28, and 30 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Matsumoto et al. (U.S. Patent No. 4,610,665) in view of Picha et al. (U.S. Patent No. 5,080,654), and Kranys (U.S. Patent No. 5,207,656). Applicants respectfully traverse the rejection.

Independent claim 22 recites:

> 22. A catheter having a vacuum seal, comprising:
> an elongate catheter shaft having a proximal end, a distal end, a guidewire lumen defined therethrough, and an inflation lumen defined therethrough;
> a balloon disposed adjacent the distal end of the catheter shaft, the balloon being in fluid communication with the inflation lumen;
> a port disposed at the proximal end of the catheter shaft, the port having an opening defined therein that is in fluid communication with the inflation lumen and a flanged end; and
> a seal member releasably attached to the flanged end and covering the opening;
> wherein the seal member does not include a preformed opening and is self-sealing such that the seal maintains a vacuum within the inflation lumen.

None of Matsumoto et al., Picha et al. or Kranys, taken alone or in combination, appear to teach or suggest a releasable seal member that does not include a preformed opening and is self-sealing such that the seal maintains a vacuum within the inflation lumen.

Matsumoto et al. appear to disclose a medical device including a valve body. The valve body appears to be configured to allow an additional medical device, such as a rod-like member, to pass through the valve body into the medical device. The valve body appears to include two slits crossing perpendicular to each other. When the additional medical device is not inserted

into the medical device, the slits appear to maintain a substantially fluid tight seal. The slits appear to allow the additional medical device to pass through the valve body while still maintaining a fluid tight seal. Once the additional medical device has been removed, the slits appear to close and again provide a substantially fluid tight seal. As acknowledged by the Examiner, Matsumoto et al. do not appear to teach or suggest a seal having a solid cross-section or a releasable seal. In formulating the rejection, the Examiner appears to rely on Picha et al. as disclosing a releasable seal and Kranys as disclosing a seal member that does not include a preformed opening.

Kranys appears to disclose a partition member that may be aperture free. It appears that the partition member may be formed from a foamed elastomer material having either an open cell or closed cell structure. In formulating the rejection, the Examiner asserts, "it would have been obvious to on having ordinary skill in the art at the time the invention was made to modify the invention of Matsumoto such that the pre-formed slits (17/18) were replaced with a seal member having a self-sealing solid cross-section. Such a modification would further ensure fluid cannot pass through the seal unintentionally." Applicants respectfully disagree. In formulating the rejection, it appears the Examiner fails to consider the limitation, "such that the seal maintains a vacuum within the inflation lumen." With respect to functional language, MPEP § 2173.05(g) states:

> **2173.05(g) Functional Limitations [R-3]**
>
> A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper. *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971).
>
> A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a particular capability or purpose that is served by the recited element, ingredient or step.

(Emphasis Added).

More particularly, *In re Swinehart* states:

> We take the characterization "functional", as used by the Patent Office and argued by the parties, to indicate nothing more than the fact that an attempt is being made to define something (in this case, a composition) by what it *does* rather than by what it *is* (as evidenced by specific structure or material, for example). In our view, there is nothing intrinsically wrong with the use of such a technique in drafting patent claims. Indeed we have even recognized in the past the practical *necessity* for the use of functional language.

(Emphasis Added) (*In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971)). As can be seen, the use of functional language is proper (and in some cases recognized as necessary), and such limitations must be evaluated and considered just like any other limitation of the claim. Moreover, and in the present case, the language the "the seal maintains a vacuum within the inflation lumen" must be evaluated and considered for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used.

While Kranys appears to disclose a partition member that is aperture free, Kranys does not appear to teach or suggest a seal that is capable of maintaining a vacuum. Kranys appears to disclose that due to the cellular nature of the foam, some fluid and/or air may pass through the partition member. For example, at column 2, lines 17-22 Kranys discloses, "An advantage of open cell foams is that they tend to be more compliant than closed cell foams, since the air in the cells can migrate to other cells as a probe passes through the partition member, stretching and expanding the member." Kranys further discloses at column 2, lines 41-45, "Also, closed cell foams provide an improvement in sealing, in that blood cannot migrate through the microstructure of the closed cell foams since there is no flow path, while with open cell foams, some blood migration might take place this way." As can be seen, Kranys appear to disclose that at least with open cell foams, some blood migration through the partition member may be expected. Furthermore, with respect to closed cell foams, it appears that once an aperture has been formed through the partition member, a pathway is created upon the removal of the guidewire or other probe (for example, the closed cells are broken during advancement of the probe). Kranys discloses at column 2, lines 23-24, "In closed cell foams, the air in the cells has no way of escape, without breaking cell walls." Thus, it appears that the partition member of Kranys allows for the passage of air and in some instances fluids. Therefore, Kranys cannot be considered as teaching or suggesting, "the seal member does not include a preformed opening

and is self-sealing such that the seal maintains a vacuum within the inflation lumen" as recited in claim 22.

Therefore, for at least these reasons, none of Matsumoto et al., Picha et al., or Kranys, taken alone or in combination, appear to teach or suggest the device as claimed. As such, the teachings of Matsumoto et al., Picha et al. and Kranys are not sufficient to render claim 22 *prima facie* obvious. For at least these reasons, claim 22 is believed to be patentable over Matsumoto et al., Picha et al., and Kranys and withdrawal of the rejection is respectfully requested. For similar reasons and others, claims 24-26, 28, and 30 which depend from claim 22 and include additional distinguishing features, are believed to be patentable over Matsumoto et al., Picha et al., and Kranys.

Claims 35 and 37 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Matsumoto et al. (U.S. Patent No. 4,610,665) in view of Picha et al. (U.S. Patent No. 5,080,654), Kranys (U.S. Patent No. 5,207,656), McClure (U.S. Patent No. 5,507,732), and Andrews et al. ("The Comparison of Commercial Getters"). Applicants respectfully traverse the rejection.

For similar reasons to those set forth above, as well as others, none of Matsumoto et al., Picha et al. or Kranys, taken alone or in combination, appear to teach or suggest "the seal does not include a preformed opening and is self-sealing such that the seal maintains a vacuum within the inflation lumen" as recited in claim Neither McClure nor Andrews et al. appear to remedy the noted shortcomings of Matsumoto et al., Picha et al. or Kranys. McClure appears to disclose seals including preformed openings which provide a friction fit with another component. McClure does not appear to teach or suggest a seal does not include a preformed opening and is self-sealing to maintain a vacuum as recited in claim 35. Andrews et al. appears to be directed towards "getters" and does not appear to teach or suggest presently claimed structure.

Therefore, for at least these reasons, none of Matsumoto et al., Picha et al., Kranys, McClure, or Andrews et al., taken alone or in combination, appear to teach or suggest the device as claimed. As such, the teachings of Matsumoto et al., Picha et al., Kranys, McClure, and Andrews et al. are not sufficient to render claim 35 *prima facie* obvious. For at least these reasons, claim 35 is believed to be patentable over Matsumoto et al., Picha et al., Kranys, McClure, and Andrews et al. and withdrawal of the rejection is respectfully requested. For similar reasons and others, claim 37 which depends from claim 35 and includes additional

distinguishing features, is believed to be patentable over Matsumoto et al., Picha et al., Kranys, McClure, and Andrews et al.

Conclusion

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Yiqun Wang et al.

By their Attorney,

Date: January 18, 2012

/j. scot wickhem/

J. Scot Wickhem, Reg. No. 41,376
SEAGER, TUFTE & WICKHEM, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, MN 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349